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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

[Docket No. 97D-0318]

Guidance for Industry:

Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products

Merck & Co., Inc. is a worldwide research-intensive company that maintains a leadership role in the pharmaceutical and biologics industry in discovery, development, production and marketing of human and animal health products. Each year since 1991, Merck has invested more than \$1 billion on research and development. Merck Research Laboratories (MRL), Merck's research division, is one of the leading biomedical research organizations, dedicated to improving human health, animal health and agriculture.

As a leading human health care company, we strongly support the concept of precautionary measures to inform patients of the possible risk to patients of transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by blood and blood products.

Merck's Comments on Proposal

Merck wishes to commend the U.S. FDA for its continued efforts to provide thoughtful and comprehensive guidance for the industry.

Because the proposed changes in the label may have significant impact on the public's concept of products that contain blood or blood-derivatives, Merck is very interested in, and well qualified to comment on this FDA Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products, hereafter referred to as The Guidance, announced in the Federal Register on August 17, 1999.

Labeling Text for Non-Implicated Products

The Guidance states that for products containing plasma-derived albumin, FDA recommends that the package insert be revised to include the following statement under WARNINGS:

97D-0318

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This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

Merck Comments:

1-Merck views the text for Non-Implicated Products as general and proposes that the wording limit the focus to CJD.

2- Due to the theoretical nature of the risk of transmission the statement, which is also noted in the guidance as precautionary measure, is considered inappropriate for inclusion in the WARNINGS section of the package insert. Specifically, 21CFR 201.57(e) describes the content of the WARNINGS section:

(e) *Warnings.* Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.

3. The statement: "Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases" is unwarranted. This imparts undue anxiety about adventitious viruses. Clearance and/or inactivation of viruses representing a broad range of physical and chemical properties has been demonstrated for the albumin process, in particular for the pasteurization step.

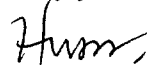
Merck Proposal:

Merck proposes that The Guidance be revised under VI. B., 4. to recommend that the following statement be inserted in the PRECAUTIONS section of the package insert:

This product contains albumin, a derivative of human blood. Although there is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), no cases of transmission have ever been identified for albumin.

We wish to thank the FDA for the opportunity to comment on The Guidance and welcome the opportunity to further discuss our comments. Questions concerning this proposal should be directed to Dr. Henrietta Ukwu (610-397-7176).

Sincerely yours,



Henrietta Ukwu, M.D.
Vice President
Vaccine Regulatory Affairs

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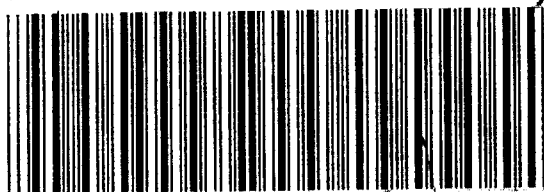
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